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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,089	03/18/2004	Gholam A. Peyman	46293	5316

1609 7590 04/01/2008

ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P.

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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

04/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/803,089

Applicant(s)

PEYMAN, GHOLAM A.

Examiner

Carlos A. Azpuru

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-31 is/are allowed.
- 6) ☒ Claim(s) 1-6, 9, 11, 13, 32-34, 37, 39-41, and 43 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 12, 14-23, 35, 36, 38, 42 and 44-46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of the terminal disclaimers filed 01/04/2008.

The rejections under the judicially created doctrine of obviousness-type double patenting over US application serial no. 10/803,090, and US Patents 6,436,429 and 7,223,416 are hereby withdrawn.

After review during a patentability conference, the following rejections were suggested for their inclusion of a bioactive and sweetener. The office is considering the blocking or suppression of pain receptors as an intended use:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 9, 11, 13, 32-34, 37, 39-41, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al.

Yang et al disclose a chewable delivery system in which an active agent is precoated with various water soluble materials. A confectionary matrix is then added to this mixture (see Abstract). Oral delivery is disclosed since the composition is well suited to taste masking, and is hydrolyzed in solution or saliva (see col. 3, lines 50-68).

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Bioactive agents include anti infectives (ie antifungals and antibacterials), antibiotics, as well as various analgesics such as acetaminophen, aspirin and ibuprofen (see col 5, lines 42-68; col. 6, lines 1-17). The method of treating is therefore inclusive of a method of temporarily relieving pain. Sweeteners used are inclusive of dipeptide sweeteners (aspartame), saccharin, and aspartame (see col. 7, lines 7-22). Dissolution in body fluids is discussed in its hydrolysis when exposed to saliva (cited above). The previously mentioned hydrolysis of the base material is proof of its water soluble characteristics. Citric acid is added at col. 8, line 25. Many of the bioactives disclosed are amines and are therefore alkaline (ie procainamide). While the reference makes no mention of the reduction or blocking of pain sensation, or blocking of pain receptors, the claims are generic to the combination of bioactive and sweetener in a treatment. The additional limitation referring to blocking of pain receptors is considered an intended use accomplished during the method of treatment by the same composition. As such, those of ordinary skill would have expected similar therapeutic effects from the instantly claimed method given the composition and method of oral delivery as disclosed by Yang et al. The instant claims would have been obvious to one of ordinary skill in the art at the time of invention given the disclosure of Yang et al.

Claims 7, 8, 12, 14-23, 35, 36, 38, 42, 44-46 are objected to as dependent upon a rejected claim.

Claims 24-31 are allowed as the topical formulation with a stabilizer does not appear to be taught by the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

Art Unit: 1615

caz